

specifically, support for Claim 1 can be found in original Claim 1. Support for the method of treatment claims can be found in the description of the figures on page 2, page 3, lines 23-27 and Examples 2 and 3 of the originally filed specification.

A search of a pharmaceutical composition for treating hepatocellular carcinoma comprising thalidomide would also include a method for treating hepatocellular carcinoma comprising administering a composition comprising an effective amount of thalidomide. Therefore, it is believed that Examiner does not have to conduct an additional search for the method of treatment claims.

### **SPECIFICATION**

Attached is a substitute specification in clean form without markings as to amended material pursuant to 37 CFR 1.125(b). Attached is a statement that the substitute specification includes no new matter and a marked up copy of the substitute specification showing the changes from the specification of record.

The amendments to the specification were to correct clerical and grammatical errors.

### **Claim Rejections - 35 U.S.C. Section 112, second paragraph**

Claims 1 and 4 were rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claims the subject matter which Applicant regards as the invention because the claims are improperly drawn to the same pharmaceutical composition.

The 35 U.S.C. Section 112, second paragraph, rejection is no longer applicable due to the cancellation of Claims 1-4.

The present set of claims are believed to be sufficiently definite to satisfy the dictates of 35 U.S.C. 112, second paragraph.

**Claim Rejection 35 U.S.C. 103(a)**

Claims 1, 2, 4-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato (U.S. Patent No. 5,593,990).

The Examiner alleges that D'Amato teaches applicants' compound thalidomide in a pharmaceutical composition for oral administration. Therefore, the Examiner alleges that one skilled in the art would find ample motivation from the prior art supra to form a pharmaceutical in the claimed range of the instant application with a reasonable expectation that said pharmaceutical composition would be effective as a pharmaceutical.

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art, *In re Royka*, 490 F.2d 981, USPQ 580 (CCPA 1974).

The present invention relates to a method of treating hepatocellular carcinoma comprising administering to a patient in need thereof a therapeutically effective amount of a pharmaceutical composition comprising thalidomide and a pharmaceutically acceptable carrier.

The Examples of the present application describe the use of thalidomide for reducing the serum alpha-fetoprotein level, GOT/GPT value and total bilirubin level of patients suffering from hepatocellular carcinoma.

U.S. Patent No. 5,629,327 does not teach or suggest a method of treating hepatocellular carcinoma comprising administering to a patient in need thereof a therapeutically effective amount of a pharmaceutical composition comprising thalidomide as described in the present invention.

U.S. Patent No. 5,629,327 relates to methods and composition for preventing unwanted angiogenesis in a human or animal by administering compounds such as thalidomide and related compounds, see col. 1, lines 14-20 of U.S. Patent No. 5,629,327.

U.S. Patent No. 5,629,327 does not describe hepatocellular carcinoma or the effects associated with this specific type of cancer. Therefore, all the claim limitations of the present application are not taught or suggested by the U.S. Patent No. 5,629,327.

In light of the above, Applicants submit that all rejections of record have been overcome. Applicants accordingly submit that the application is now in condition for allowance and respectfully request action in accordance therewith.

Respectfully submitted,

JOHN RICHARDS  
LADAS & PARRY  
26 WEST 61<sup>ST</sup> STREET  
NEW YORK, NY 10023  
REG. NO.31053(212) 708-1915